ALLERGAN

2525 Dupont Drive, P.O. Box 19534, Irvine, California, USA 92623-9534 Telephone: (714) 246-4500 Website: www.allergan.com

November 5, 1999

Dockets Management Branch
Division of Management Systems and Policy
Office of Human Resources and Management Services
Food and Drug Administration
5630 Fishers Lane, Room 1061 (HFA-305)
Rockville, MD 20852

Re: Docket No. 99D-2212
Draft Guidance On Quality Systems Regulation Information For Various Premarket Submissions

In response to the Federal Register Notice of August 3, 1999, Allergan, Inc. is hereby commenting on the above-cited draft guidance document.

Allergan appreciates the promulgation of guidance intended to clarify Agency expectations regarding data and information to be provided in marketing applications. Nonetheless, we respectfully submit that the documentation to be required, per the proposed guidance, is in excess of that which is necessary for FDA to meet its statutory mandate and is, therefore, unduly burdensome. In particular, we believe the guidance should be modified as follows:

- The requirement for providing a design control dossier and a manufacturing dossier for ***every PMA supplement*** is unwarranted. FDA has recently published the "Draft Guidance: Likelihood of Facilities Inspections When Modifying Devices Subject to Premarket Approval." We recommend that the requirements for submission of QS Regulation information be limited to those 180-day PMA supplements where a pre-approval inspection is "likely" per the cited draft guidance. Further, once a manufacturer has submitted a manufacturing dossier to a specified PMA, 180-day supplements should only be required to include information that differs from that submitted previously.

  Similarly, only those PMA supplements requesting approval for design changes should require design dossiers, with the level of required information commensurate with the significance of the design change. For example, a PMA

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supplement for a labeling change to add a new claim could be adequately addressed by providing information on the design change procedures by which the new labeling was qualified.

- The requirement for manufacturers to have a design control dossier available, upon request, for devices subject to 510(k) clearance suggests that such documentation could be requested as part of the determination of substantial equivalence. Substantial equivalence determinations should be based on the comparison of the proposed device to a legally marketed predicate device and ***not*** based upon review of the design procedures.

- The requirement for manufacturers to maintain design control dossiers ***at their manufacturing facility*** to support premarket notifications is also unwarranted. Each facility should only be required to maintain Quality System Regulation information relevant to procedures conducted at that site. Thus, where all design is performed at another site, the required design control information at the manufacturing site should be limited to the change control procedures in effect at that site.

- We believe that Item #3 on page 9 of the draft guidance, which states that a manufacturer should highlight its lack of expertise with a new process (when validating something for the first time), is highly inappropriate. This infers that such manufacturers' validations will be scrutinized at a much higher level than validations performed by other manufacturers. We believe it is important that FDA apply consistent criteria in its review of all marketing applications.

Thank you for the opportunity to comment on this draft document. Please feel free to contact me if you require further information on this matter.

Sincerely,

Marcia S. Yaross, Ph.D.
Director, Worldwide Regulatory Affairs
and Medical Compliance

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